Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VII Issue 1 January 2002

Laboratory Conference Summary

by Leonard Kargacin

Dennis Weissman presented the opening keynote address for the 8th Annual Clinical Laboratory Conference that was held on November 12, 2001, in Seattle. His presentation was titled "National Healthcare Policy Developments and Outlook: What Can Labs Expect." The following is a brief synopsis of this presentation.

Laboratory-Related Legislation in the 107th Congress

- H.R. 1948 - Medical Laboratory Personnel Shortage Act
- H.R. 1451/ S. 730 - Physician Pathology Services Fair Treatment Act
- H.R. 1202/ S. 258 - Providing Annual Pap Tests to Save Women's Lives Act of 2001
- H.R. 602/S. 318 - Genetic Nondiscrimination
- H.R 1798/S. 1066 - Medicare Patient Access to Preventive and Diagnostic Tests Act
  - Eliminates carrier variation in Medicare payment in 2002 by setting lab fees at the National Limitation Amount (NLA)
  - Allows CPI update for lab fees in 2002
  - Specifies that payment should not differ for similar tests
  - Sets NLA at 100% of the national median for tests previously gap-filled (3-year process after assignment of HCPCS code)
  - Bars CMS from delegating coding and payment decisions to regional office or local contractor
  - Prohibits CMS from assigning a code to a new test that differs from the code recommended by CPT and results in lower payment because test is waived under CLIA

Legislative Outlook: Domestic issues, including patients' rights and a Medicare prescription drug benefit, will take a back seat to national security issues.

Inside This Issue

Pathology Payment:

- A "grandfather" provision allows independent labs to continue to bill Medicare globally through 2002 for the technical component (TC) for both inpatient and outpatient anatomic pathology services as long as arrangements were in place on or before July 22, 1999. The laboratory must forward a copy of its agreement with the hospital or other documentation (Transmittal AB-01-47) to its carrier. If the contract was oral or cannot be found, an attestation will suffice (Transmittal B-01-50 specifies what information is required).
- Pathology received a 2% increase in Medicare fees in 2001
- Medicare Part B spending for pathology services would increase by 3% in CY 2002 under changes to the physician fee schedule payment method proposed in August 2001
- Pap smears - national minimum Medicare payment is $14.60 and $28.00 for monolayer methods
- Effective April l, 2002, Medicare set national limitation amount (NLA) for 12 cytopathology codes for diagnostic and screening Pap smears

Institutes of Medicine (IOM) Lab Payment Study was mandated by Congress in the 1997 Balanced Budget Act. The study describes the lab industry in depth, analyzes trends in technology, and weighs the pros and cons of current Medicare payment methodology and alternatives. The conclusions of the study can be found in the report, "Medicare Laboratory Payment Policy: Now and in the Future," that can be accessed online at www.nap.edu.

Uniform Lab Payment Rule, published March 2000; final rule expected late 2001 or early 2002

- Curtails discretion of local Medicare contractors to limit coverage of lab tests
- Clarifies or codifies documentation and record keeping requirements plus claims review procedures used by contractors

continued on page 2

Laboratory Conference, continued from page 1

- Includes uniform coverage and payment policies included for 23 lab procedures
- Labs and contractors can request diagnosis information from MDs but they don't have to comply
- Claims Processing and Documentation:
  - Physician is responsible for maintaining medical necessity documentation in the beneficiary's medical record
  - Lab submitting a claim is required to maintain documentation it receives from the ordering physician, along with information documenting that the claim accurately reflects information received from the doctor
- Claims Review - Labs must provide the following when requested by contractors:
  - Documentation of the physician's order for the service billed
  - Documentation showing that the test order was accurately processed and claim properly submitted
  - Diagnostic information provided by doctor to lab by ordering physician (include ICD-9 code, etc.)
- CMS Instructions to Contractors:
  - Clarifys term "screening"
  - Notice of frequency screens
  - Proper use of modifiers (multiple testing)
  - No requirement for physician's signature
  - Labs may code narrative diagnosis
  - Handle limited # of claims on forms
  - Match diagnosis to procedure

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DOH home page: http://www.doh.wa.gov
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- Definition of date-of-service is still unresolved

Revised Advanced Beneficiary Notice (ABN) Format
CMS adopted a standardized ABN format with separate forms for lab and other Part B services
- Two-page form approved by OMB
- Labs may use new format (CMS-R-131-L) but not required until final instructions issued
- Beneficiary is given two options on form: (1) agreeing to receive lab tests and allowing Medicare to decide if it will pay for the service or, (2) deciding not to receive the lab tests

Stark II Final Rule
- Prohibits referring Medicare/Medicaid patients for designated health services to facilities with which the physician (or an immediate family member) has a financial relationship, whether by ownership or investment interest or a compensation arrangement
- Phase I published January 4, 2001, but not effective until January 4, 2002
- Phase II will be published later and address Medicaid and other issues

OIG Priorities for 2002
- No letdown in fraud and abuse enforcement but new emphasis of working with provider community is expected
- New OIG compliance guidance due for ambulance companies, pharmaceutical companies, and mental health service providers in 2002

Congressman James McDermott

by Leonard Kargacin

Congressman James McDermott (D-WA) presented the luncheon keynote address at this year's conference. In his presentation, Congressman McDermott briefed the participants about Congress and some of the pending legislation that affect laboratories. The following article is a brief synopsis of his presentation.

Representatives McDermott and Jennifer Dunn introduced H.R. 1798 into the House of Representatives. H.R. 1798

continued on page 3

Congressman James McDermott, continued from page 2

is called the Medicare Patient Access to Preventive and Diagnostic Test Act. When it was introduced, it was felt that there would be a budget surplus at the national level and that there was a good chance that the bill would pass out of Congress. However, events on September 11 and since have changed that outlook entirely.

If passed, H.R. 1798 would improve the payment policy for laboratory tests. According to Congressman McDermott, federal payment policies have to be sufficient to maintain access to new and innovative diagnostic tests. This is in line with what the recent Institutes of Medicine (IOM) report on Medicare reimbursement concluded. H.R. 1798 incorporates several of the recommendations from the IOM report. It would:

- Reform the coding and payment systems for diagnostic tests in ways that will help Medicare keep pace with innovation.
- Provide a transparent and public process to insure that patients, providers, and manufacturers can comment on Medicare's proposed payment for new technologies.
- Establish a single national fee schedule for clinical laboratory tests to simplify the payment process.
- Update the payments for laboratory tests that have been frozen since 1997.

Congressman McDermott stated that by reforming the process by which the Medicare system integrates innovative tests into the delivery system, patients would be able to benefit nationwide from the many advances of science and technology. As the IOM study points out, the problems in Medicare policy for diagnostic testing have a much broader impact than just Medicare. They also affect Medicaid and many private health care plans that follow Medicare's lead. Whatever Medicare does has far reaching effects.

Last year in Congress, 5,680 bills were introduced. Congressman McDermott stated that no one legislator can possibly know what is in all of those bills. Members of Congress have to vote on about 1,200 issues in a given year. It is an impossible job to keep up with all of these issues. Therefore, he encouraged everyone to play a part in helping to educate the Congress about issues of concern. Advocacy is very important both in terms of educating members of Congress and staff about specific problems that confront you, and helpsd to design policies that will actually work.

According to Congressman McDermott, individuals can have a tremendous impact by educating members of Congress and their staff. We should think of ourselves as being part of the system. He encouraged us to go down to our Senators' and Representatives' offices or invite them to come into our laboratory and explain to them what we do. One picture is worth a thousand words! Not only should we show them how tests are performed, but we should also show them the complexities of the billing process. Congressman McDermott stated that we can have a tremendous impact by doing this. The more this is done throughout the country, the more likely that legislation that helps laboratories will actually pass. In this way, laboratory personnel can become the experts who members of Congress will contact when they need information on a specific issue.

Congressman McDermott commented that it was unclear what was going to pass in this Congress since the events of September 11. In addition, since both Houses of Congress are pretty balanced, it is difficult to pass legislation without a great deal of political maneuvering. In the midst of all of this, bioterrorism has come on the scene. Bioterrorism has become the health care priority and has made people realize how important the public health system is. This will help to increase the public's awareness of the important role that the clinical laboratory plays in the nation's health.

Future Issues of Elaborations!

Look for highlights from other sessions at the 8th Annual Clinical Laboratory Conference in future issues of Elaborations

Clinical Microbiology Initiative

by Jon M. Counts, Dr.PH, MPH

A questionnaire survey was distributed in July to all Washington microbiology laboratories to assess current laboratory practices in antimicrobial susceptibility testing (AST). The preliminary assessment of data obtained from the survey is found below.

Good News

- 72% return rate on questionnaires
- Majority of respondents indicate that they are using NCCLS standards
- Majority of laboratories indicate that they interact with medical, pharmacy staff and/or utilize NCCLS guidelines to determine # and type of antibiotics to be tested

Quality Improvement Needed

- Only 40% of respondents indicate that they are using the most current NCCLS tables. (Majority of small community hospital, commercial, and physician office laboratories do not utilize current NCCLS tables.) Only the most recent tables have the current zone interpretive criteria, QC ranges and other guidelines that aid in resistance detection.
- Percent of respondents who provided the appropriate answer, as determined by the authors, to the different scenarios (case studies) ranged from 22-59%. (Small community hospital, commercial, and physician office laboratories did not perform as well as urban hospital laboratories). Scenarios address a contemporary antimicrobial susceptibility testing issue.
- There was lack of consistency noted in the number and type of antimicrobials that laboratories used for testing invasive isolates of *Streptococcus pneumoniae.* (This was noted in all categories of laboratories and continues as a problem previously noted in earlier studies). Latest WA DOH report on drug resistant *Streptococcus pneumoniae* (DRSP) indicates that 79.8% of isolates were tested appropriately with both penicillin (or Oxacillin) and an extended spectrum cephalosporin. Data collected prior to June 1998 pointed out that only 64% of isolates were tested appropriately**.**
- Priority training needs in order of priority: 1) selection of drugs for testing; 2) enhancing patient reports for interpretation of results; 3) susceptibility testing for which there are no NCCLS standards; 4) susceptibility testing for which NCCLS standards exist; 5) assessment of competency in antimicrobial susceptibility testing.
- Recommended educational activities which would be most beneficial in order of priority: 1) video taped lectures; 2) off-site training; 3) on-site training; 4) lectures on CD-rom.
- Deficiencies identified in study of referral laboratory services, published in Pacific NW Laboratory Medicine Sentinel Monitoring Network report (2000), need to be evaluated and appropriate steps taken to correct.
- Personnel in small hospital laboratories expressed concern about their ability to provide appropriate clinical microbiology services in their facilities.
- Majority of respondents (>75%) are not familiar with Washington Clinical Laboratory Advisory Council practice guidelines that were developed to guide clinicians in the appropriate utilization of laboratory testing for infectious diseases.

Potential Impact of Deficiences Noted in Survey

- Utilization of outdated NCCLS charts may contribute to erroneous results leading to treatment failures and false assumptions about antimicrobial resistance.
- Failure to respond appropriately to case studies reveals a level of competence by individuals performing AST, which may contribute to inappropriate and costly testing.
- Failure to utilize appropriate number and type of antimicrobials in AST may contribute to treatment failures and insufficient data on antimicrobial resistance in an institution or local community.

The Data was Presented to and Discussed with the Following:

- Initiative Steering Committee
- Clinical Laboratory Advisory Council (CLAC)
- Show & Tell (Puget Sound microbiologists)
- Directors of clinical laboratory training programs
- Pierce County Antibiotic Resistance Task Force
- Statewide videoconference for personnel in clinical microbiology laboratories

The following intervention strategies will be implemented in 2002 as part of the quality improvement phase of this initiative:

- Videoconference – overview of QA in clinical microbiology and AST
- "Train the Trainer" workshop that will help develop a core capacity of local individuals who are knowledgable in the latest standards and recommendations for AST. These individuals will serve as faculty for technical workshops and videoconferences. They will also function as consultants to provide technical assistance to clinical laboratories.
- Technical workshops and/or videoconferences will be sponsored to address specific technical issues in AST, utilizing CD-roms and the *MASTER* website developed by CDC (www.phppo.cdc.gov/dls/master/default.asp).
- A website for the initiative will be implemented.
- NCCLS CD-roms, videotapes and publications on AST performance standards have been provided to the PHL Training Program for distribution to clinical laboratories

continued on page 5

Clinical Microbiology Initiative, continued from page 4

- CLAC practice guidelines will need to be developed to aid clinicians in the utilization of laboratory testing for antimicrobial resistance
- Information on initiative and quality improvement strategy will be disseminated to appropriate health care and medical associations
- Focus group discussions will be scheduled to address the following issues:
  - Factors and criteria that are used in selecting laboratory methodology/technology and testing policies for infectious disease agents
  - Evaluation of referral laboratory system and development of recommendations for improvment
  - Factors and criteria that could be used to establish the level of clinical microbiology services that should be provided by public and private sector laboratories
  - The need to survey physicians and laboratories to determine their satisfaction with microbiology services and practices provided by in-state and out-of-state laboratories
- Develop additional strategies in response to recommendations provided by Steering Committee, CLAC, Laboratory Quality Assurance staff and others.

The following is an article on the activities of the Antibiotic Resistance Task Force in Pierce County.

Microbiology Lab Consensus Approach to Standardized Antimicrobial Susceptibility Testing in Pierce County

By David Tison, Ph.D., ABMM, FAAM
TPCHD Antibiotic Resistance Task Force, Surveillance Committee Chair
Clinical Microbiologist, MultiCare Health System, Tacoma

A multi-disciplinary task force, organized by the Tacoma-Pierce County Health Department (TPCHD), was convened in late 2000 to address issues regarding increasing antibiotic resistance in Pierce County. One aspect of the project involves compiling antimicrobial susceptibility data on a countywide basis. Microbiology laboratory representatives from throughout the county met to agree on a standard format for submitting data.

Upon review of the first combined susceptibility results, it became apparent that microbiology laboratories were using different schemes for susceptibility testing, particularly for *Streptococcus pneumoniae*. Some laboratories were doing MIC testing for blood/CSF (invasive) isolates while other labs were using the oxacillin disk screen for penicillin resistance as their initial susceptibility test. If the isolate was susceptible using the oxacillin screen, no further testing was done. Oxacillin resistant strains were tested with additional antimicrobials. This testing scheme resulted in a turnaround time of 48 hours for susceptibility results of oxacillin/penicillin resistant strains of invasive *S. pneumoniae*. This scheme also resulted in a lack of data for other antimicrobials which affected the cumulative susceptibility surveillance data.

The microbiology laboratory group reconvened to discuss issues around susceptibility testing of invasive *S. pneumoniae.* The benefits of initial MIC testing for producing reliable and more rapid susceptibility results, and the contribution to improved patient care were discussed. The group agreed to a scheme of MIC testing of penicillin and a third generation cephalosporin using the agar gradient method. The group also agreed to testing of a macrolide and fluoroquinolone that could easily be accomplished by disk diffusion on the same plate as the MIC test. The disk susceptibility data would be for surveillance purposes.

Our experience is an example of how cooperation among laboratory colleagues can result in improved laboratory practices which benefit our patients.

If you have question about this article, please contact Dr. Tison at (253) 403-2209 or by e-mail at david.tison@multicare.org.

Waived Testing Helpful Hints

√ Be sure to use only the specimen type for which the waived test was intended (i.e., whole blood, not serum or plasma).

√ Refer to your product insert sections entitled "Intended Use" and "Specimen Collection, Handling, Storage" for information about the correct specimen type, acceptable anticoagulants, acceptable time delays, and specimen storage prior to testing.

√ Using the proper specimen is one of the essential elements in performing an accurate test.

NOTE: Check this spot in future editions of Elaborations for more helpful hints with waived testing.

Calendar of Events

PHL Training Classes:
Point of Care Testing
June 21 Shoreline

WSSCLS/NWSSAMT Spring Meeting
April 25-27 Everett

Northwest Medical Laboratory Symposium
October 16 - 19 Portland

9th Annual Clinical Laboratory Conference
November 11 Seattle

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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